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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,536	06/05/2006	Andrea Piva	HOFF-38826	4428

86378 7590 01/19/2010

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EXAMINER
MARX, IRENE

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
01/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,536	PIVA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-28* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 12/04/09 is acknowledged.

Claims 20-28 are being considered on the merits. Claims 16-19 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the proviso in claim 20 of "said Pediocin A being present in said composition independently from said bacterial strain". There is no clear indication in the as-filed specification how any "independence" is achieved, implemented and maintained. The term "independently" is not clearly defined in the as-filed specification. The meaning intended for "independently" in this context cannot be readily ascertained, particularly since the claimed method requires administering "a pharmaceutical composition comprising Pediocin A **in combination with** at least one bacterial strain…".

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is vague, indefinite and confusing in that the intended meaning of "increasing the health of an intestine of a monogastric species" is not readily ascertainable. It is not apparent that there is more than one intestine in a monogastric species. In addition, the extent of increase intended is not set forth with any particularity.

Claim 20 is vague, indefinite and confusing in that the meaning of "independently" in this context cannot be readily ascertained, even when reading the claims in light of the specification. See, new matter rejection *supra.*

The term "independently" is not clearly defined in the as-filed specification. If it is intended to mean that compositions are provided at different times, this interpretation is directly contradicted by the recitation at line 4 stating the method comprises administering "a pharmaceutical composition comprising Pediocin A **in combination with** at least one bacterial strain…".

Claims 20-28 are vague, indefinite and confusing in that the "effective" amount to be administered would depend on the composition provided and the monogastric species to be treated as well as the intended results desired and their extent or degree. A plethora of diverse monogastric species are known having diverse metabolic needs including insects, elephants, fish, dogs, cats, fowl, pigs, humans, etc.

In this regard, claims 21-28 are confusing in the addition of intended results to the method of claim 20 without any changes in the process, i.e., in the composition provided or in the process steps. In addition, the effective amount cannot be readily ascertained, as noted *supra.* Moreover, the desired results of claims 21-27 do not appear to be particularly correlated with "sanitary conditions of the intestine". Is the "effective amount" the same in every instance?

Claim 23 is confusing in the recitation of "deputed to the absorption of nutrients". It is unclear what is intended in this context.

Claim 27 lacks antecedent basis in claim 20 for "Pediocin A analogous molecules". In addition, the molecules intended are not clearly defined, since the extent of analogy cannot be readily ascertain in this context.

Claim 28 appears redundant in that "prevention" and "prophylaxis" appear to be substantial synonyms. In addition, there is no clear correlation between the "effective amount" to enhance sanitary conditions and the requirements of claim 28.

Applicant did not address the rejection. The rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *P. pentosaceus* designated FBB63. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that no deposit was made in this application that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's proffer of a page of a reference stating that the strain FBB63 is from different culture collections is not probative of public availability of this strain, since the culture collections are not identified by name. Thus there is no indication of the specific collections intended and it cannot be determined whether or not the strains "were readily available to the public at the time of the invention" from a recognized depository as baldly asserted by applicant.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piva *et al.* (1995) of record taken with Piva *et al.* (1994) (Microbiology, 140 (4): 697 and Mishra *et al.* (Asia Pacific J Clin Nutr (1996) 5: 20-24).

The claims are directed to a method of increasing the health of an intestine or prophylaxis of *C. perfringens* infections by administering certain *P. pentosaceus* strains and Pediocin A and providing certain additional functional results.

Piva *et al.* (1995) teach the treatment of caecal contents of a monogastric animal with a combination of *Pediococcus pentosaceus* ATCC 43200 and pediocin A. The results obtained demonstrate the favorable effects of the combination of *Pediococcus pentosaceus* ATCC 43200 and pediocin A and suggest to one of ordinary skill in the art the benefits of administering such a combination *in vivo* to improve digestion throughout the gastrointestinal tract, including the intestine, of course by avoiding excessive proteolysis, for example. See, e.g., Discussion, page 619. The further results desired would flow naturally upon administration of the same composition as is administered by applicants to a monogastric animal.

The reference differs from the claimed invention in the prevention of *C. perfringens* infection. However, Piva 1994 disclose the beneficial effects of at least Pediocin A in inhibiting certain *Clostridium* (See, e.g., Table 2). One of ordinary skill in the art would reasonably have expected further strains to be sensitive to this bacteriocin since almost all of the Gram positive strains tested were sensitive to Pediocin A. See, e.g., page 700, col. 1, penultimate paragraph.

Moreover, the added presence of the strain *per se* would also be effective at least in competitive exclusion of *C. perfringens* in the intestine of a monogastric species.

In addition Mishra *et al.* disclose the favorably properties of lactic acid bacteria in general as probiotics, as well as the favorable inhibitory properties of Pediocin A. See, e.g., Table 2.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Piva *et al.* (1995) by administering the combination of *Pediococcus pentosaceus* ATCC 43200 and pediocin A to a monogastric species for the expected benefits of improving the digestive process in monogastric species and in addition prevent colonization by pathogenic bacteria such as *C. perfringens*.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that in Piva *et al.* (1995) the cells are washed and lack Pediocin A. However, from the Discussion at page 619 it is clear that Pediocin A is produced by strain *P. pentosaceus* FBB61 and that both the cells and Pediocin A are present in the mixture. It is submitted that they are "independent" at least to some extent. There is no claim designated limitation to require to "add" Pediocin A as argued. It is noted that the pharmaceutical composition administered in the claim designated invention comprises Pediocin A in combination with the bacterial strain. The effect would be the same whether Pediocin A is added or produced *in situ.*

Moreover, Piva *et al.* (1995) recognizes that there are significant effects due to the strain and due to Pediocin A in the cecal fermentation, such as decrease in ammonia. Therefore, the reference clearly suggests an increase of health in an intestine of a monogastric species due to Pediocin A combined with *P. pentosaceus* FBB61. The effect is absent in the strain that does not produce Pediocin A.

Regarding the prophylaxis of *C. perfringens* infections, it is submitted that administration of the composition to the animal would have the natural effect of preventing the infection, even this is not specifically recognized by the references.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651